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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/023,483	02/13/98	HEROUX J	2528-2

HM22/0304

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EXAMINER	
TUNG, J	
ART UNIT	**PAPER NUMBER**
1634	6

DATE MAILED: 03/04/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/023,483	Applicant(s) Heroux et al.
	Examiner Joyce Tung	Group Art Unit 1634

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits** is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-37 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-37 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1634.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. These claims are vague and indefinite because of the abbreviation "NTP". It is suggested to use a full name of the term.

b. Claim 15 is vague and indefinite because of the language "said at least one label" which has not antecedent basis from where it is recited.

c. Claims 26 and 33 are vague and indefinite because in the claims there is no a polymerase corresponding with having an NTP present. It is not clear how amplification is carried out without a polymerase.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3, 6-12, 14-25, 28-32 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley (5,043,272) in view of Eberle et al. (5,413,906).

Hartley discloses a random amplification method and kit using a random oligonucleotide primer in which the method uses at least one primer (see column 5, lines 10-24), which may be substituted with biotin (see column 6, lines 39) which is detectable species; having promoter site for RNA polymerase which is binding species; attached to a solid phase through using a linker (see column 9, lines 35), and at least one dNTP used in the method (see column 10, lines 5). There are also capture probe to capture the amplified products on magnetic beads (see column 12, lines 13 and 40-43). The primer is 8 bases long preferred and other length such as 4-mer, 5-mer

can be used (see column 6, lines 19-24). The polymerase is Klenow fragment of DNA polymerase I (see column 4, lines 60). The reaction mixture contains pH 6.8, 400uM of the final concentration of dNTP, 5mM of magnesium and 10mM of 2-mercaptoethanol which is a reduce agent. The reaction contains at least one dNTP (see column ~~4~~ 10, lines ~~27-30~~ 1-8).

The teachings of Hartley suggest instant claims 1-3, 6-12, 14-25, 28-32 and 34-37 in which a random primer at least 4 nucleotides in length and having detectable species or binding species is used, the mixture is contacted with a solid support and a kit is constructed. The detectable species are as listed in instant claims 7, 15 and 28, the binding species are as listed in instant claims 6 and 16, the polymerases are as listed in instant claims 8, 17, 21 and 29, the solid supports are as listed in instant claims 9 and 18, and the dNTP is as listed in instant claims 10, 19 and 30, the condition of the method is listed in instant claim 12 and 32, and the length of the primer is listed in instant claims 11, 14, 20 and 31.

[mg] = 0.05 – 500mM

Hartley dose not disclose one dNTP which has binding species or detectable species. and/or of molecules optionally

Eberle et al. disclose a method for determining polymerase activity in which a detectable mononucleoside triphosphate and immobilizable nucleoside triphosphate binding to a solid support are used (see column 2, lines 27-49, column 3, lines 50-68 and column 4, lines 1-21).

The teachings of Eberle et al. suggest one dNTP having at least one detectable species in instant claims 1-3 and 23-25. The detectable species is selected from the group consisting biotin in instant claims 7, 15 and 28.

One having ordinary skill in the art would have been motivated to combine these two references at the time when the invention was made to get reasonable expectation of success because the method of Hartley is for amplifying nucleic acid without prior knowledge of the sequence and it does not require complex handling or repeated intervention on the part of the technician performing the method (see column 9, lines 5-13) and the method of Eberle et al. provide a quick, simple more reliable and sensitive test (see column 2, lines 27-30). Thus it would have been prima facie obvious to carry out the method as claimed.

5. Claims 4, 5, 13, 26, 27 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartley (5,043,272) in view of Wu et al. (Genomics, 1989, vol. 4, pg. 560-569) and Respess (5,599,662).

The teachings of Hartley are set forth in paragraph 5.

Hartley dose not disclose using a ligase and the labeled primer having binding species in the method.

Wu et al. disclose a ligase amplification system used as an allele-specific detection with T4 DNA ligase (see pg. 561, first column, 2nd paragraph).

Respess discloses a method which involves an improved primer which is biotin labeled and has binding species since the amplified products hybridize to a bound probes. It indicates that there are binding species on the primer (see column 12, lines 29-31).

. The teachings of Wu et al. and Respess suggest instant claims 4, 5, 13, 26, 27 and 33 in which a random primer labeled and having binding species is used and a ligase is involved. The ligase is listed in instant claims 13 and 33.

One having ordinary skilled artisan in the art would have been motivated to combine these references at the time when the invention was made to get reasonable expectation of success because the method of Hartley is for amplifying nucleic acid without prior knowledge of the sequence and it does not require complex handling or repeated intervention on the part of the technician performing the method (see column 9, lines 5-13), the improved primer of Respess also more specifically amplifies a target without the simultaneous amplification of non-target sequences (see column 1, lines 58-67 and column 2, lines 1-4) and the method of Wu involves a ligase for allele- specific detection. It would have been prima facies obvious to carry out the method as claimed.

6. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1634 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

February 23, 1999

ARDIN H. MARSCHEL
PRIMARY EXAMINER